EXHIBIT 46

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCT MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION ***This Document Relates to All Cases***	**Civil Action No. 3:16-md-2738- MAS-RLS** **MDL No. 2738**

EXPERT REPORT OF

BERNARD L. HARLOW, Ph.D. and KENNETH J. ROTHMAN, Dr.P.H.

November 15, 2023

Talc and Ovarian Cancer Review;

Expert report written by Bernard L Harlow, Ph.D. and Kenneth J Rothman, DrPH

November, 2023

MANDATE

We have been retained to review the current state of the science regarding whether genital application of talcum powder products, including Johnson & Johnson Baby Powder and Shower to Shower, causes epithelial ovarian cancer in women who use them for genital hygiene.

CREDENTIALS, EXPERTISE, AND EXPERIENCE

Bernard L Harlow, PhD

Dr. Harlow is a Professor of Epidemiology at the Boston University School of Public Health (BUSPH). Formerly, he was the Mayo Professor and Chair of the Division of Epidemiology and Community Health at the University of Minnesota School of Public Health for 10 years. Before becoming Chair in Minnesota, Dr. Harlow was an Associate Professor of Ob/Gyn and Reproductive Medicine at Brigham and Women's Hospital and Harvard Medical School, and Associate Professor of Epidemiology at the Harvard School of Public Health. During that 18-year period, he Co-Founded and Co-Directed The Ob/Gyn Epidemiology Center at Brigham and Women's Hospital.

Dr. Harlow is an elected member of the American College of Epidemiology and an active member in the Society for Epidemiologic Research, where he served as President Elect, President, and Past-President from 2015 and 2018. In addition, he served as a member of the Board of Scientific Counselors for Clinical Sciences and Epidemiology of the National Cancer Institute and Chaired or participated in numerous NIH Scientific Grant Review Study Sections. Dr. Harlow received the Gaylord W Anderson Leadership Award while at the University of Minnesota School of Public Health and recently received the Boston University School of Public Health Excellence in Research Mentoring award.

Dr. Harlow received his PhD in Epidemiology in 1987 from the University of Washington. For the past 35 years, he has focused on epidemiologic research specifically in women's cancers and other benign gynecological disorders. With respect to research on perineal exposure to talc and risk of ovarian cancer, he either led or was involved in publishing 4 peer-reviewed scientific articles between 1987 and 1999 and a letter to the editor in 2020 (see below). In addition, he received multiple NIH grants to lead a large prospective study of depression and premature menopause (The Harvard Study of Moods and Cycles), and multiple NIH grants to lead studies on the prevalence and etiology of unexplained vulvar pain. Dr. Harlow has published approximately 160 peer reviewed scientific articles and has several currently in process or under review. He served on the editorial board for the American Journal of Epidemiology and has reviewed manuscripts for over a dozen prestigious journals including: JAMA, Epidemiology, Journal of the National Cancer Institute, and New England Journal of Medicine, to name a few.

Dr. Harlow is particularly well suited to evaluate the merits of the research on talc and ovarian cancer because of his expertise in methods of data collection. Early in his career, he worked for Westat, Inc, an outstanding data collection company in the Washington DC area. During that time, he developed questionnaires and managed the data collection process for numerous large-scale epidemiologic studies for the National Cancer Institute. Recently, he developed a graduate level course on Data Collection Methods at Boston University that educates future public health researchers about how to collect data that can adequately capture the relevant details on exposures that are needed to assess their associations with adverse health outcomes. He currently conducts a Grant Writing Workshop for faculty at Boston University that focuses on developing the most scientifically appropriate methods for data collection to address a particular research hypothesis. Finally, he teaches a course on Guided Epidemiology Research where students identify an important public health research question, develop the most appropriate analytic approach, carry out the analyses, interpret the findings, and then write the results up for publication in the scientific literature.

Below are citations for Dr. Harlow's 4 published research articles and one letter to the editor with Dr. Rothman:

Harlow BL, Weiss NS. A case-control study of borderline ovarian tumors: the influence of perineal exposure to talc. Am J Epidemiol. 1989;130(2):390-4.
Harlow BL, Cramer DW, Bell DA, Welch WR. Perineal exposure to talc and ovarian cancer risk. Obstet Gynecol. 1992;80(1):19-26.
Harlow BL, Hartge PA. A review of perineal talc exposure and risk of ovarian cancer (Review). Regulatory Toxicology & Pharmacology 1995;21(2):254-260
Cramer DW, Liberman RF, Titus-Ernstoff L, Welch WR, Greenberg ER, Baron JA, **Harlow BL**. Genital talc exposure and risk of ovarian cancer. Int J Cancer. 1999;81(3):351-6.
Harlow BL, Murray EJ, **Rothman KJ**. Re: Genital Powder Use and Ovarian Cancer. JAMA. 2020;323(20):2096. doi:10.1001/jama.2020.3858.

Dr. Harlow has never testified as an expert at trial or deposition. His compensation for preparing this report was $600 per hour.

Kenneth J. Rothman, DrPH

Dr. Rothman is a Professor of Epidemiology at Boston University and a Distinguished Fellow Emeritus at the Research Triangle Institute. He has authored or co-authored over 500 epidemiologic publications, including many research studies relating to environmental epidemiology. His main career focus, however, has been the development and teaching of epidemiologic research methods. He has authored two epidemiology textbooks, *Epidemiology – An Introduction*, currently in its second edition, and *Modern Epidemiology*, first published in 1986 and now in its fourth edition. *Modern Epidemiology* is the leading advanced textbook in its field, used worldwide for doctoral training in epidemiology. In addition, he was the editor of a book published in 1988 entitled *Causal Inference,* which focused on the considerations that guide inferences about causal connections. Both *Modern Epidemiology* and *Causal Inference* are cited in the Federal Judicial Center's *Reference Manual on Scientific Evidence (Third*

Edition). Dr. Rothman's published work has been cited in the biomedical literature more than 100,000 times.

Dr. Rothman was the founding editor of the journal *Epidemiology*, and an Editor of the *American Journal of Epidemiology.* He was also a member of the Editorial Board of two leading medical journals, the *New England Journal of Medicine* and *The Lancet*. He is the recipient of the American College of Epidemiology's Lilienfeld Award for Excellence in Epidemiology, the Society for Epidemiologic Research's Career Accomplishment Award, the International Society for Pharmacoepidemiology's Sustained Service Award, and an honorary MD degree from Aarhus University in Denmark. Early in his career, he served as President of the Society for Epidemiologic Research, the primary professional society for research epidemiologists. This society now bestows an annual award called the Kenneth Rothman Career Accomplishment Award.

He has written landmark papers on the topic of causation and causal inference. One paper, entitled "Causes," published in 1976 in the American Journal of Epidemiology, was honored as a "Classic Paper" contribution to the epidemiology literature by the Journal in 1995. He has been an invited lecturer at the Food and Drug Administration, the Centers for Disease Control, and many universities within the U.S. and abroad. Over a period of 50 years, he has taught invited courses on epidemiologic study design and analysis at various locations, including the University of Minnesota, Erasmus University, University of Oslo, Tufts University, Massachusetts Institute of Technology, the Karolinska Institute, the University of North Carolina, the University of Washington, Ohio State University, University of Auckland, Teikyo University, the University of Utah, and many others.

Dr. Rothman was the author of a report in 2000 on the relation between talc and ovarian cancer that was commissioned by talc manufacturers, and a co-author of a letter to the editor of the Journal of the American Medical Association, with Dr. Harlow and Dr. Eleanor Murray. He has not testified on this topic at trial or deposition. His compensation for contributing to the current report was $1000 per hour.

OVERALL APPROACH AND METHODOLOGY OF THIS REVIEW.

Attempts to infer whether an environmental agent is a cause of a given disease are often submitted to a set of checklist-type conditions, such as those attributed to Austin Bradford-Hill.[1] The work of several philosophers of science, however, such as David Hume, Karl Popper, and others, have shown that there is no checklist approach that will serve as a logical template for identifying causes. If all it took for a valid inference about causation were to check off a list of criteria, science could follow a recipe. Any time that an association was consistently observed between an exposure and a disease, the conditions for causality could be checked and causal connections could be identified or rejected. Unfortunately, despite the fact that purported lists of causal criteria have been proposed and implemented, a valid set of such criteria does not exist. Bradford-Hill himself stated:

"What I do not believe ⋯ is that we can usefully lay down some hard-and-fast rules of evidence that must be observed before we accept cause and effect. None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a sine qua non." [1]

Bradford-Hill knew that the list of conditions he spoke about was riddled with exceptions that defeated the purpose of any checklist for causation. For example, one of his criteria was strength of association, based on the idea that strong associations tend to be causal and weak associations are likely to be non-causal. Nonetheless, many strong associations are not causal. For example, there is a strong association between birth rank and Down syndrome, with first-born having lowest risk and later born babies having higher risk. This strong association is not causal; it is entirely explained by the association between mother's age and Down syndrome. Conversely, many associations known to be causal, such as the association between cigarette smoking and cardiovascular disease, are weak. If strong associations may be non-causal and weak associations may be causal, strength of association is hardly a criterion for causal inference. Similar analysis shows that none of Bradford-Hill's list of considerations is a reliable criterion that separates causal from non-causal associations.

If no checklist for causal inference exists, then how does causal inference proceed? When it comes to determining whether an observed association is causal, epidemiologists proceed by posing alternative non-causal explanations to account for the association. An example of such an alternative explanation would be, can chance explain the association? Or, was the association attributable to some other factor that causes the disease and is associated with the exposure under study? Suppose we find that there is an association between coffee drinking and cancer of the urinary bladder. One might hypothesize that some component of coffee acts to cause bladder cancer. Alternatively, a non-causal explanation would be that coffee consumption is greater among tobacco smokers than nonsmokers, and that it is smoking rather than coffee drinking that causes an increase in occurrence of bladder cancer. In fact, the latter explanation is thought to be correct. If tobacco smoking is then controlled in the study design or the data analysis, the association between coffee drinking and bladder cancer will

disappear and the causal theory about coffee and bladder cancer will be refuted. The point is that epidemiologists make their inferences by pitting alternative explanations against one another. This approach amounts to pitting non-causal theories against a causal theory. Epidemiologists ask, “Is there some systematic error in the data from a study? Then let’s control that problem and see what association if any remains between exposure and disease.”

Apart from chance, epidemiologists use a term to describe, collectively, the range of non-causal explanations that compete with the idea of cause and effect. The term is ”bias.” This term has a broader meaning in the epidemiologic context than it does in ordinary parlance. In epidemiology, “bias” can refer to a prejudicial mindset, but it is more generally used to describe any type of systematic error that will distort the results of a study, in either direction. Thus, many biases are the product of errors in data, or problems with study design, or other factors that do not involve investigator prejudices. As explained above, epidemiologic inference about causation largely involves ways of trying to remove or to assess biases to determine whether the observed association is valid. If no bias can be found to explain an association that is observed consistently across many studies, the causal theory may begin to look like the most reasonable explanation for the observed association. This process of pitting competing theories against one another better describes how causal inference proceeds in epidemiology than does the application of checklists of supposed causal criteria.

EXECUTIVE SUMMARY

Keeping in mind the methodology described above, we have reviewed the epidemiologic literature regarding the possible carcinogenic effect of perineal talc exposure on the ovaries, along with relevant information from other scientific disciplines. As mentioned, checklist approaches such as the list of criteria taken from a talk by Bradford-Hill cannot be a dispositive method of causal inference in empirical science. Rather, a causal hypothesis must be weighed against non-causal explanations of an association.

Most of the epidemiologic data that exist come from older studies, but there have been recent publications that combine these older studies into summary meta-analyses. The principal finding from the literature is a consistent association between frequent talc use and ovarian cancer, an association that is stronger and more consistent for the subtype of serous ovarian cancer. Some reviewers are inclined to ascribe the association to recall bias in case-control studies, but published methodological reviews show that recall bias typically has a negligible effect, and in our opinion, it is not plausible that recall bias can explain away the association. We note that there is also an association between talc use and ovarian cancer in cohort studies. Although such associations are weaker, they are expected to be weaker because cohort studies often have worse exposure assessment for chronic exposures that vary over time. Inaccuracies in exposure assessment typically lead to underestimates of associations. Biologically, talc has been shown to migrate through the female reproductive tract to the fallopian tubes and ovaries, and has been shown to contain asbestos particulates, which are known to be carcinogenic. Those studies that were able to assess continuous use of talc over decades showed strong associations within those populations.

Overall, the persistent association between talc use and ovarian cancer is not readily explained by any non-causal hypothesis. It is our opinion that causation is the most reasonable explanation for the association between perineal exposure to talc and ovarian cancer.

SCIENTIFIC REPORT

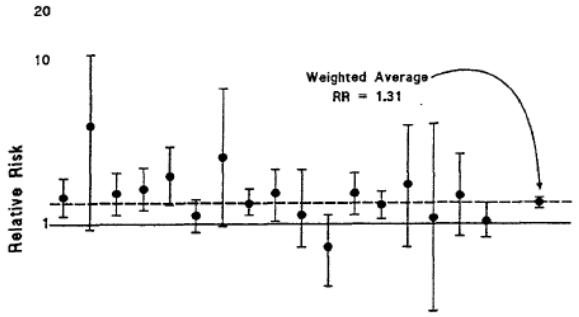
Interest in talc exposure dates back to the 1960's, when excess risk of ovarian cancer was observed among female asbestos workers. Talc (platy talc and talc fibers) and asbestos are structurally similar and occur in nature together, so the application of talc to the genital area has been an object of research over nearly 4 decades as a possible cause of ovarian cancer. The causal hypothesis involves the plausible mechanism that talc applied directly to the genital area or undergarments may migrate through the cervix to the fallopian tubes and ovaries, where it has a carcinogenic effect.

In the following sections we provide a brief overview of findings from prior case-control and cohort studies, focusing on potential biases and limitations associated with this research. We then summarize reviews of articles published between 2018 and 2023. All are meta-analyses, critical reviews, or commentaries on the earlier body of literature that includes dozens of case-control studies and four cohort studies that have examined this association. It should be noted that many of the studies used in these meta or pooled analyses overlap. As far as we know, no study involving collection of new data related to perineal exposure to talc and ovarian cancer has been reported since 2016.

A. Case-control Studies

The majority of observational studies that have examined this association were case-control (sometimes described, inaccurately, as retrospective studies). These studies produce estimates of the risk of ovarian cancer among talc users, relative to the risk among nonusers of talc. The ratio of these risks is termed the "risk ratio" (also referred to as "relative risk"). It is estimated by comparing women with and without ovarian cancer with respect to their previous use of talc. As seen in an unpublished report in 2000 by Rothman *et al.*, a weighted average of study specific relative risk estimates from 16 earlier case-control studies yielded an estimated risk ratio of 1.31 with a narrow confidence interval[a] around this estimate (Figure 1). This value, if valid, would imply a 31% greater risk for ovarian cancer among talc users.

Figure 1
Study-specific Relative Risk Estimates for Ovarian Cancer Among Talc Users, and Overall Weighted Average of Study Results



[a] A confidence interval defines a range of values for the measure of interest that would be considered more compatible with the data than values outside the range, if the statistical model and all its assumptions are correct. (Greenland *et al*., Statistical tests, P values, confidence intervals, and power: a guide to misinterpretations. Eur J Epidemiol (2016) 31:337–350 DOI 10.1007/s10654-016-0149-3)

A 2008 published meta-analysis of 14 general population case-control studies reported that women who had used talc had a risk ratio for ovarian cancer of 1.4, which is to say that they were estimated to have a 40% greater risk for ovarian cancer than women who had not used talc. The corresponding 95% confidence interval around the estimate ranged from 1.30 to 1.52.[2] There was an unusual degree of consistency across these 14 studies, with all but two reporting risk ratio estimates between 1 and 2. The other two studies reported risk ratio estimates greater than 2. A more recent pooled analysis published in 2013 of 8 studies (6 USA, 1 Australian, and 1 Canadian) as part of the Ovarian Cancer Association Consortium (OCAC) reported that women with perineal talc exposure had a risk ratio of 1.24 for ovarian cancer (a 24% greater risk), compared with women with no talc exposure. The 95% confidence interval around this estimate ranged from 1.15 to 1.33.[3] Seven of the 8 studies reported risk ratio estimates in the range from 1.13 to 1.36. All histological subtypes of epithelial ovarian cancer were found to be associated with talc exposure, with the strongest association seen for women with serous ovarian tumors.

The most recent studies that reported newly collected data were published in 2016; they confirmed earlier findings. The first, by Cramer *et al.*,[4] studied more than 2000 women with ovarian cancer and compared them with a control series of 2000 women without ovarian cancer. Those reporting perineal use of talc had a risk ratio estimate of 1.33, with a 95% confidence interval of 1.16—1.52. Women with more than 20 years of daily genital talc exposure had a nearly 40% greater risk of ovarian cancer relative to nonusers (OR=1.39, 95%CI 1.11-1.75). There was a clear trend of increasing risk with increasing exposure, and a strong dose response relation with heavier and longer exposure. The second study by Schildkraut *et al.*[5] was among African-American women where those with talc exposure were 44% more likely to develop ovarian cancer than those with no talc exposure, also showing a trend of increasing risk with increasing years and frequency of exposure.

B. Cohort Studies

There are 4 cohort studies that have attempted to assess this association: The Nurses' Health Study I and II, The Sisters Study, and the Women's Health Initiative.

Nurses' Health Study: The Nurses' Health Study comprises a pair of cohort studies of U.S. nurses who enrolled in the study and have been followed for decades with respect to a range of outcomes. In 2000, Gertig *et al.* [6] reported on the nurses' experience with ovarian cancer according to their self-reported history of talc exposure. They found an overall multivariate adjusted risk ratio of 1.09, with a 95% CI of 0.86-1.37. They also reported an estimated risk ratio of 1.40 (95% CI 1.02--1.91) for invasive serous ovarian tumors. The latter measure was 1.51 (95% CI 1.07--2.15) when the analysis was restricted to women who were 45 years of age or older in 1982. This restriction served as a proxy for identifying talc exposure that was used in earlier times and was more likely to contain greater amounts

of asbestiform fibers. However, we have since learned that asbestiform fibers have been detected within talc even in studies as recent as 2020, when it was reported that talcum products used by 8 out of 10 women who developed serous ovarian cancer contained tremolite and/or anthophyllite asbestos. [7] In addition, an analysis of Johnson and Johnson's talcum power between 1960 and 2000 found evidence that talc has contained asbestos and talc fibers, and the FDA tested Johnson & Johnson's baby powder in 2019, finding asbestos and talc fibers.[b]

Women's Health Initiative: In 2013, Houghton *et al.*[8] reported an overall risk ratio of 1.12 for ovarian cancer among women who applied "powder" to their genital area (95% CI 0.92--1.36), compared with women who did not apply "powder." The multivariate adjusted hazard ratio for serous ovarian tumors was 1.16 (95% CI 0.88--1.53). In women who applied powder to both the genital area and to their diaphragms, the risk ratio was 1.45 (95% CI 0.95--2.23). Although we cannot determine whether "talc" as opposed to other non-talc powders such as cornstarch were used by these participants, a possible concern is that only women older than 50 years of age were included. Thus, about half of ovarian cancers, those cancers that occur in women

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Table 1. Jeffrey T. Quirk, Nachthu Natarajan, Ovarian cancer incidence in the United States, 1992–1999, Gynecologic Oncology, Volume 97, Issue 2, 2005, Pages 519-523. [9]

Descriptive characteristics of microscopically confirmed ovarian cancer cases, SEER 1992–1999[a]

Classification	*N*	%[b]	Age (median)	Age distribution (%)			Racial distribution (%)			
				<30	30–59	≥60	White	Black	Other	Unknown
All ovarian cancer	23,484	100.0	60.0	5.0	43.1	51.9	85.3	6.4	7.7	0.5
All epithelial	22,378	95.3	61.0	3.5	43.3	53.2	85.9	6.0	7.6	0.5
Serous	9734	41.4	60.0	4.2	45.1	50.7	87.3	6.1	6.1	0.6
Mucinous	3229	13.7	52.0	8.8	54.3	36.9	82.7	6.0	10.7	0.6
Endometrioid	2997	12.8	58.0	1.1	52.5	46.4	86.0	5.0	8.5	0.5
Clear cell	892	3.8	55.0	0.6	61.5	37.9	80.9	3.9	14.8	0.3
Other epithelial	5526	23.5	70.0	1.1	25.5	73.4	85.9	6.9	6.7	0.4
Germ cell	614	2.6	26.0	58.0	32.6	9.4	74.8	12.1	12.5	0.7
Sex cord-stromal	293	1.2	50.0	12.3	57.3	30.4	70.0	21.8	7.5	0.7
Other ovary	199	0.8	70.0	3.5	28.2	68.3	80.9	11.6	7.0	0.5

less than 50 years of age, would have been missed (See table above). Women over age 50 are less likely to have a patent genital tract, which makes the true talc exposure more difficult to quantify. This problem would result in nondifferential misclassification of actual exposure and likely underestimation of any effect.

[b] Amended Expert Report of William E. Longo, PhD and Mark W. Rigler, PhD (February 2, 2019) (finding that 68% of the samples tested contained amphibole asbestos and 98% contained fibrous talc or talc fibers); Exhibit 28, Hopkins Dep. (Aug. 16 & 17, 2018; Oct. 26, 2018); AMA Analytical Serv., Certificate of Analysis (Oct. 3, 2019) (FDA commissioned testing finding chrysotile asbestos and talc fibers).

Sisters Study: In 2016, Gonzalez *et al.*[10] reported a hazard ratio of 0.73 for ovarian cancer occurring after use of talc 12 months before enrollment (95% CI 0.44--1.2), in a cohort study of women whose sisters had developed breast cancer, and were therefore at higher risk themselves for ovarian cancer than most women.[10] These results, showing a negative association between talc and ovarian cancer, are anomalous. We note that the measured exposure to talc only included exposure within the past 12 months, whereas most research in this area indicates that it is long-term use of talc that is associated with the greatest risk.

C. Recent Meta Analyses and Commentaries published between 2018 and 2023 (in chronological order by year)

1) Berge, Mundt, Luu, and Boffetta, 2017 [11] **-** The authors carried out a meta-analysis based on the Preferred Reporting items for Scientific Review and selected 24 case-control studies, 3 cohort studies, and one pooled analysis of 8 of the 24 case control studies. The pooled relative risk estimate from all 27 studies for any genital talc use was 1.22 (95%CI 1.13-1.30). Although the authors state that they *"identified a small but statistically significant association between genital talc use and risk of ovarian cancer*", they state that it was largely limited to serous ovarian tumors and that the *"heterogeneity of results between case control studies and cohort studies do not support a causal interpretation of the association.*"

There are many dubious statements and analytic assessments of the data throughout this manuscript; we will try to point out the most pertinent. First, the authors present results that are consistent with other meta analyses showing that perineal talc exposure was associated with a 20-30 percent greater risk of ovarian cancer. The authors put greater weight on the cohort studies, stating that the reason for the smaller effect estimates in cohort studies cannot be explained by power: *"low power of cohort studies cannot be invoked as explanation of the heterogeneity of results."* Yet, there is no discussion of the limitation of exposure assessments in cohort studies, which we discussed above.

The authors also state: *"The fact that the association between genital talc use and risk of ovarian cancer is present in case–control, but not in cohort studies, can be attributed to bias in the former type of studies"* and they cite Dr. Rothman's 3rd edition of Modern Epidemiology, published in 2008. Presumably the authors are referring to recall bias, which is a possibility in some case-control studies but not in cohort studies. However, no evidence is offered that recall bias is actually present in the case-control studies. Although it is often assumed that case-control interview-based studies will be affected by recall bias, the magnitude of error from this mechanism has not often been examined. When it has been examined, the evidence shows that it is not an important concern. For example, Drews *et al.* [12] showed that for a large number of recalled variables, there was negligible bias when the recall of parents of children who succumbed to sudden infant death syndrome was compared with the

recall of parents whose children had not suffered this outcome. In another evaluation of recall bias, Paganini-Hill and Ross [13] found little error in recall comparing women with breast cancer with controls in recalling past medication use and medical history: *"There was no evidence on Interview of cases preferentially recalling more drug use or past diseases than controls."* Furthermore, Drews and Greenland [14] showed that, even with differential recall, the effect on the magnitude of association in a study is often mathematically negligible: *"under many circumstances recall bias may have limited impact on study validity."* [14] Thus, despite commonly expressed concern about recall bias, it is far from established that it is an important concern in any but a few case-control studies. We note that Berge *et al.* do not offer any evidence that recall bias actually poses a problem in these talc case-control studies.

From a biological perspective, the authors state "talcum powders for domestic use in the USA have been virtually asbestos free since the 1970s." and cite a reference from 1976. Berge *et al.* published their paper in 2017. As described above in the discussion of the Nurse's Health Study, analyses of J&J talcum powder from the 1960s to 2019 have demonstrated the presence of asbestiform fibers (asbestos and talc) in USA talc products. Another paper, published in 2020, found that 10 women diagnosed with serous ovarian cancer who had documented use of J&J cosmetic talcum powder all had talc and 8 of the 10 had asbestos in samples of their ovarian tissue.[7]

2) Penninkilampi and Eslick, 2018[15] - These authors conducted a systematic review using the PRISMA guidelines for meta-analysis: "Preferred Reporting Items for Systematic review and Meta-Analyses." A summary of the 27 studies included showed a 24 to 39 percent excess risk of ovarian cancer associated with perineal exposure to talc. The authors stated that the 25% greater risk of serous ovarian cancer observed in the 3 cohort studies provided evidence that offset the concern related to recall bias potential in the case-control studies.

3) Goodman et al., 2020:[16] These authors published a critical review of the talc and ovarian cancer literature and concluded that the evidence across all scientific disciplines does not support a causal association. We believe that many statements in this review are inaccurate. We summarize a few of them here:

Statement 1: *"Some case control studies and meta-analyses reported associations, while other case control investigations, and three large prospective studies, and a pooled analysis of cohort investigations found this association to be null."*

Of the 33 studies presented by the authors, they highlighted 18 that they deemed "statistically significant" for either any use or perineal application of talc. However, only two of the 15 remaining studies showed risk ratio estimates of 1.0 or lower. The other 13 studies reported risk ratio estimates in the range of 1.2 to 2.5. As discussed above, there are substantial scientific biases that can affect

cohort studies that the reviewers failed to integrate into their assessment. As shown throughout this report, most meta-analyses support associations with point estimates and confidence intervals that are highly compatible with harmful effects.

Statement 2*: "In summary, the prospective cohort studies consistently reported a null association …..talc exposure was not associated with increased risks of any subtypes of ovarian cancer, and associations did not appear to vary by subtype."*

This statement ignores the finding from The Nurses' Health Study, which reported a risk ratio of 1.4 (95% CI 1.02--1.91) for serous ovarian tumors, which comprise the large majority of invasive ovarian cancers. The estimate of 1.4 is consistent with the magnitude of the association observed across the majority of all epidemiologic studies.

Statement 3: "*Our analysis of the epidemiology studies indicates that there is a small, increased association observed between perineal talc and ovarian cancer in some case control studies. In contrast, in meta-analyses, despite the above observations, there is no consistent finding of a positive exposure-response relationship."*

The authors of this review specifically discuss the pooled analysis of 8 studies from the Ovarian Cancer Association Consortium.[3] That analysis found an overall estimated risk ratio for any talc use of 1.24 (95% CI 1.15--1.33); furthermore, the authors stated that for genital talc application *"most studies demonstrat(ed) significant elevated risks".*

Statement 4: "*A striking feature of the body of epidemiology evidence regarding talc and ovarian cancer is the difference in results reported between case-control and cohort studies."*

In our view, the case-control and cohort study results show reasonable consistency, especially if one focuses on the reported findings that are most scientifically relevant to this research question. As mentioned above, the WHI and the Sisters Study had problematic exposure assessments for talc. The NHS collected information about talc exposure only during the first NHS study, using their 1982 questionnaire, and reported an overall multivariate adjusted risk ratio of 1.09 (95%CI 0.86-1.37), a risk ratio of 1.40 (95%CI 1.02-1,91) for invasive serous ovarian tumors, and a risk ratio of 1.51 (95%CI 1.07-2.15) when restricted to women 45 years of age or older in 1982.

Furthermore, this statement carries an implication that cohort studies and case-control studies should reach identical results, and if they do not, the cohort studies automatically have greater validity, based on the presumption that case-control study results are less reliable than the cohort study results. We disagree with this implied premise. In many circumstances, case-control studies may offer greater

validity than cohort studies. Cohort studies are not well suited to assess associations between exposures and outcomes that span long periods of time, unless an exposed cohort can be followed continuously for that long period and the exposure information updated, which is often impractical or impossible. Case-control studies, in contrast, can readily assess associations that span many years or decades. For example, a single case-control study of adenocarcinoma of the vagina, with only 8 cases and 32 controls, sufficed to demonstrate beyond any doubt that exposure to diethylstilbestrol *in utero* caused the development of vaginal cancer when the exposed female fetuses became adults.[17] If the research question involves the action of a cause over a period of a decade or many decades, as appears to be the case for talc and ovarian cancer, we would expect case-control studies and cohort studies to differ in their ability to measure these associations. Our expectation, however, is that there would be less bias in the case-control studies, if they are properly conducted, than in cohort studies. In our opinion, most of the cohort studies that have addressed the talc and ovarian cancer association failed to assess talc exposure adequately across the life-course, with a consequent bias that likely leads to underestimation of the talc-ovarian cancer relationship.

4) O'Brien et al., 2020-[18] These investigators pooled the NHS I and II, the WHI, and the Sisters Study to assess the pooled estimate of ovarian cancer risk in relation to perineal exposure to talc among the published cohort studies. This analysis therefore incorporates the biases we have mentioned in our description of the cohort studies above. Nonetheless, even with these biases, which would underestimate the association, the pooled analysis showed an adjusted hazard ratio (HR)[c] of 1.13 (95% CI 1.01--1.26) for ever use of talc in those with a patent genital tract. The authors concluded that "there was not a statistically significant association between self-reported use of powder in the genital area and incidence ovarian cancer." In a letter to the editor after publication,[19] Harlow *et al*. noted that the HR of 1.13 was actually greater than the estimated 10% increased risk shown among those with an intact genital tract who reported 10,000 or more applications across their lifetime.[20] In their response, O'Brien *et al.* agreed that *"our results, particularly the analysis limited to women with intact genital tracts, should not be discounted because of lack of statistical significance"*. Considering the exposure misclassification issues present in the cohort studies and likely underestimation of effect, this pooled result of 1.13 is reasonably compatible with the results from the case-control studies.

5) Taher et al 2020 [21] **–** The authors conducted a meta-analysis using 24 case control studies and 3 cohort studies. They reported a pooled overall relative risk estimate of 1.28 (95%CI 1.20--1.37), indicating comparability with other pooled analyses. As seen in other meta analyses, relative risk estimates in the cohort studies were lower. In this analysis, the author assessed frequency of talc use based on three groups: high (once daily for >25 days/month), medium (once daily for 10–25 days/month) and low (once daily for 1–<10 days/month). The OR for the high-use group was greater (OR=1.39, 95%CI 1.22-1.58) than that for the other two groups (OR=1.22, 95%CI 1.0-1.5). Although the

[c] A hazard ratio is an epidemiologic measure that for practical purposes may be considered equivalent to a risk ratio.

trend with number of years of use was not substantially different, the authors did not take into account frequency of use and length of use simultaneously in their analyses. A cumulative measure that combines both might be even more informative. Nonetheless, the authors conclude: *"Consistent with a previous evaluation by the IARC in 2010, the present evaluation of all currently available relevant data indicates that perineal exposure to talc powder is a possible cause of ovarian cancer in humans*."

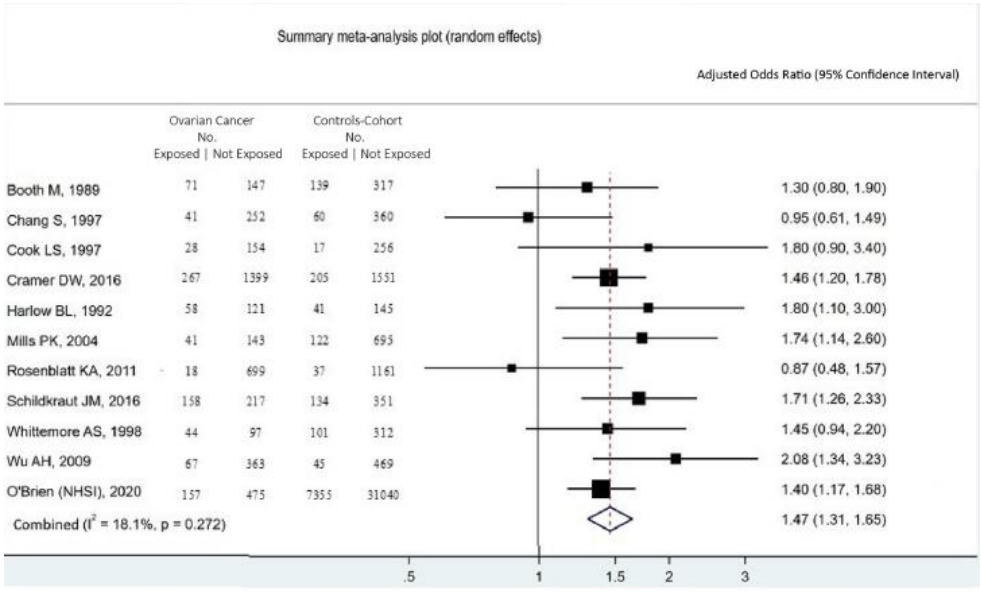
6) Davis et al 2021 [22] **–** The authors pooled all studies of ovarian cancer that had at least 40 cases of ovarian cancer in African American (AA) women from the Ovarian Cancer of Women of African American Ancestry pool of case-control studies. Analyses included 620 cases of ovarian cancer in AA women and 2800 cases in white women. The authors found an association consistent with that observed in most case-control studies, with 20-40 percent excess risk estimates present in both AA and white women. They also observed little difference in risk by histologic subtype. Their analysis of a possible dose-response relation was limited to those who used talc <1 time/week compared with those who used talc >1 time/week). They concluded that *"there was not a dose–response relationship between frequency or duration of genital powder use".* Their dose-response analysis did not combine frequency with duration of use to get a cumulative exposure measure. The authors concluded while the prevalence of ever use of genital body powder was higher among AA women in the OCWAA consortium, the association between genital powder use and ovarian cancer risk was similar among AA and White women. We note that there is no reason to think that a smaller or greater prevalence of exposure would change the magnitude of the effect of the exposure, so the conclusion should not be considered surprising.

7) Health Canada Screening Assessment of Talc – 2021[d]

This report was issued by the Offices of the Minister of the Environment and the Minister of Health in Canada. Upon their review of the literature pertaining to perineal exposure of talc and ovarian cancer, they concluded that *"the data are indicative of a causal effect*." Although not published in a scientific journal, this public-health assessment was critically reviewed by scientists within the Canadian government and others within Canada with expertise in this area.

[d] Screening Assessment; Talc. Government of Canada. April 2021

8) Woolen et al., 2022-[23] These authors conducted a meta-analysis based upon the Meta-analyses of Observational Studies (MOOSE) reporting guidelines. There were eleven studies that met the stringent quality assessment of frequent talc exposure (10 case control, 1 cohort study). Three of the four cohort studies did not meet the exposure assessment criteria. The pooled risk ratio for the association with frequent talc exposure was 1.47 (95% CI 1.31--1.65) as shown here.



9) Micha, Rettenmaier, Bohart, and Goldstein Commentary 2022 [24] **–** These authors published a commentary questioning the evidence for a talc and ovarian cancer association. The authors state that *"perineal application of talc does not conclusively render vaginal or cervical permeation, much less ovarian infiltration."* In fact, multiple studies have now shown the presence of talc in both fallopian tubes and ovarian tissue. The authors state *"there have been rare, histopathologic cases of talc identified in the lymph nodes, cervix and uterine corpus and fallopian tubes."* In our discussion below regarding the biological plausibility of an association, we cite a paper by McDonald *et al.* [25] in 2019 specifically showing talc particulates in many of these anatomical areas.

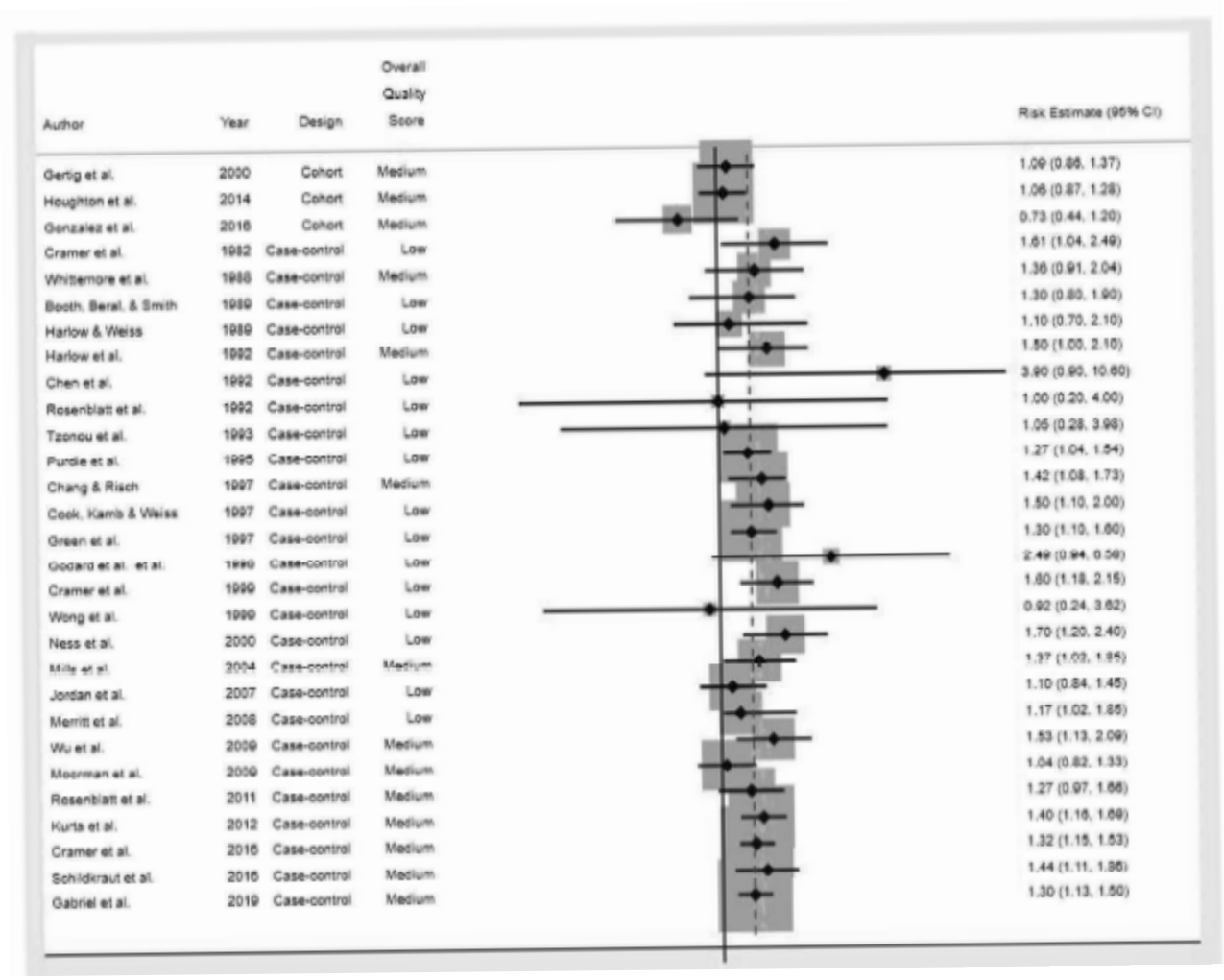
The authors state: *"While several case control studies have suggested a relationship between talc powder and the incidence of ovarian cancer, numerous epidemiological studies have refuted any such association."* It appears that the authors are equating refutation with a lack of statistical significance, which is a well-understood fallacy. Refuting an association requires a confidence interval that is narrow and is near the null value, which is a condition that none of the studies meet. One need only review the summaries of these studies that we have described above to see that this statement is indefensible.

The authors also state that in case-control studies *"both prior and subsequent talc exposure to a cancer diagnosis was assessed, thereby confounding the rates between case and control study subjects*." Though they described this as a confounding issue, it is not one of confounding but instead an issue of exposure misclassification. Furthermore, contrary to their implication, in the recent study by Cramer *et al.* [4], and in the earlier study by Harlow *et al.* [20], exposure to talc was only assessed before first

diagnosis of ovarian cancer in cases, and a matched reference age in controls, to ensure both temporality and comparability of exposure assessment.

The authors go on to cite the findings from the cohort studies, which we have already addressed above.

10) Lynch et al., 2023 [26] – The authors ranked studies according to USA EPA designated five methodological domains (participation, exposure assessment, outcome assessment, confounding control, and analytic approach). In the figure below, virtually all studies showed risk ratio estimates above 1.0.



D. National Cancer Institute, Physician Data Query (PDQ)

The PDQ cancer information summaries are peer-reviewed, evidence-based summaries on topics including adult and pediatric cancer treatment, supportive and palliative care, screening, prevention,

genetics, and complementary and alternative medicine. The review is done by an outside committee appointed by the NCI. These PDQ cancer information summaries are updated periodically. The association between Talc and Ovarian Cancer has been addressed consistently over the past 20 years. In 2013, the PDQ summary labeled talc exposure as a "*Factor with adequate evidence of increased risk of ovarian cancer."* The statement indicated: *"Based on solid evidence, perineal application of talc is associated with a small increased risk of ovarian cancer. The IARC has concluded that perineal talc is a possible carcinogen."* However, a few years later, in 2016, and in each subsequent report up to the present, the PDQ drew a different conclusion, as illustrated in their most recent 2023 summary of the scientific evidence: *"Results from case-control and cohort studies are inconsistent, so the data are inadequate to support an association between perineal talc exposure and an increased risk of ovarian cancer."*

In our review above, we have discussed the recall bias issue and the exposure assessment deficiencies observed in the cohort studies. The one cohort study that had the most appropriate exposure assessment reported findings similar to those of the case-control studies.[6] In this recent PDQ report, the authors stated that the study with the strongest association between talc and ovarian cancer reviewed by Woolen *et al*. was a *"highly selected subset analysis.*" In fact, this was the Nurses' Health Study, and it was selected by Woolen *et al.* based on the review of the actual data collected showing that adequate exposure assessment was performed. As we have pointed out, the other cohort studies suffered from both selection bias of participants and inadequate assessment of talc exposure. The PDQ committee indicated that the finding of a 1.47 pooled risk ratio estimate (95%CI 1.31-1.65) for "frequent" use of talc, cited by Woolen *et al., "was inconsistent with the main findings."* The meaning of this statement is unclear, but the PDQ committee goes on to cite the Gertig *et al.* analysis (incorrectly cited in the PDQ report as O'Brien et al) that reported a multivariate adjusted relative risk for any perineal talc use of 1.09 (95%CI 0.86-1.37). However, they fail to mention the finding of a risk ratio estimate of 1.26 (95%CI 0.94-1.69) for any serous tumor, and a finding of 1.4 (95%CI 1.02-1.91) for invasive serous tumors. In addition, they failed to mention that when *Gertig et al*. restricted the analysis to women 45 years of age or older in 1982, the relative risk for invasive serous tumors was 1.51 (95%CI 1.07-2.15). In the next section below, we discuss the assumptions being made about the superiority of cohort studies over case-control studies and how cohort studies can spuriously underreport true associations.

E. Addressing skepticism related to this research

There are many concerns that have been raised related to the quality of the studies published and the biological rationale for such an association. Below, we address narratives used to refute these findings.

1. Recall bias can easily explain the associations

Recall bias is a concern when the health outcome influences the recall of particular antecedent exposures of interest. This is most relevant in interview-based case-control studies where there is concern that study participants with the disease or adverse health outcome will either under- or over-report an exposure due to the influence of knowing that they have the outcome being studied. First, as described above, when recall bias has been measured in various settings, it has often been shown to be inconsequential [12-14]. Furthermore, even when there is differential recall, its effect on the observed association may be minor. [14] In addition, errors in exposure categorization can and do occur in cohort studies, many of which involve interviews or questionnaires requiring recall of past events. If such errors occur before the study outcome occurs, the errors will not depend on knowledge of the outcome and will typically lead to underestimation of the association. These errors will tend to bias cohort study results toward the value of no effect, a bias opposite to that presumed to occur from recall bias in case-control studies. In our opinion, daily use of talc over long periods or decades is unlikely to be recalled inaccurately. It was this type of use, daily over many years, that was reported to be most strongly associated with ovarian cancer.[4,20]

2. Case-control studies are inferior to cohort studies

Dr. Rothman has written on this research misconception:

"Discrepancies between cohort studies and case–control studies should not be explained away superficially by a presumed validity advantage for cohort studies over case–control studies. Properly designed case–control studies will produce the same results as properly designed cohort studies. When conflicts arise, they could stem from problems in either or both types of study. Although case–control studies have long been disparaged as being backwards versions of cohort studies, starting from disease and tracing back to possible causes, epidemiologists today understand case–control studies to be conceptually identical to cohort studies, apart from an efficiency gain that comes from sampling the denominators rather than conducting a complete census. Indeed, the efficiency gain may allow more resources for exposure assessment or case validation in case–control studies, resulting in less bias than in corresponding cohort studies of the same relation." [27]

In short, both cohort and case-control studies will yield valid results when properly conducted. When the outcome of interest is relatively rare, as for most cancers, the case-control study is more efficient, and as mentioned above, may be a better tool for studying exposure-disease connections that bridge long time spans. As we have shown, the findings from the Nurses' Health Study are comparable with those observed in the multiple case-control studies. The exposure assessment issues in the Women's Health Initiative and the Sisters study may explain why their results diverge from the other studies.

3. Only statistically significant associations provide evidence of a causal effect.

A consensus is slowly building among scientists that statistical significance testing has been a source of many errors in interpretation, and should be avoided. There is a considerable literature addressing this issue. One recent commentary in *Nature* by Amrhein, Greenland and McShane, and endorsed by 800 signatories[28], stated:

"We should never conclude there is 'no difference' or 'no association' just because a P value is larger than a threshold such as 0.05 or, equivalently, because a confidence interval includes zero. Neither should we conclude that two studies conflict because one had a statistically significant result and the other did not. These errors waste research efforts and misinform policy decisions."

Thus, if a lower 95% confidence interval for a risk ratio is 0.99 in one study, and 1.01 in another study, that is no basis for reaching a different interpretation for the findings. Statistical significance testing should be avoided, and confidence intervals should be interpreted as general indicators of the magnitude of the effect size.

The consensus statement from the American Statistical Association mentioned above states:

"*A p-value, or statistical significance, does not measure the size of an effect or the importance of a result…. By itself, a p-value does not provide a good measure of evidence regarding a model or hypothesis…. Scientific conclusions and business or policy decisions should not be based only on whether a p-value passes a specific threshold."*

4. There is a lack of evidence regarding the biological plausibility of talc-induced carcinogenesis.

Documenting the presence of talc particulates in the fallopian tubes and ovaries would be necessary to show the migration of these particulates through the genital tract. In earlier studies that documented the presence of talc in ovarian tissue, there was skepticism that the potential for talc contamination via surgical procedures may have explained the findings. However, a recent study by McDonald *et al.* [25] used polarized light microscopy and in-situ scanning electronic microscopy (SEM) with energy-dispersive x-ray analysis (EDX) to differentiate particulates that may be due to contamination. Five women with documented perineal talc exposure and ovarian cancer all showed pelvic migration of talc particulates and the existence of morphologically demonstrated talc in multiple pelvic organ sites, including pelvic tissues and lymph nodes. None was found in the negative exposure controls.

Recent studies have also suggested that the formation of cancer in the ovaries could be seeded from a primary tumor in the fallopian tubes involving changes in key genes such as TP53, PTEN, and BRCA1 or BRCA2. [29] Thus, the migration of talc may not need to travel into the ovaries to have a carcinogenic effect. Although the exact pathogenic mechanism by which talc may incur carcinogenesis is unknown, plausible mechanisms may involve inflammation.

E. Summary

Considering the preponderance of evidence, including

a) similar findings across dozens of studies;
b) after controlling for known risk and protective factors for ovarian cancer, evidence of a trend of increasing risk of ovarian cancer with increasing talc applications, especially when the vaginal tract is open to the ovaries; and
c) the presence of talc particulates within ovarian biopsied tissue;

it appears to us that the most plausible interpretation of the existing data is that women exposed to talc for a long period of time are at greater risk of developing ovarian cancer than women who were never exposed, as a result of their talc exposure. Although the evidence continues to accumulate, the risk of ovarian cancer as a consequence of perineal exposure to talc has been suspected for over 40 years. Over 30 years ago, in a 1992 publication, Dr. Harlow wrote that approximately 10% of the incidence of ovarian cancer in the U.S. may be attributable to this exposure. He also recommended then that given the poor prognosis for ovarian cancer, potentially harmful exposures with limited benefits should be avoided. Since then, the evidence for an association between perineal talc exposure and ovarian cancer has increased. During these decades, an application of the Precautionary Principle would seem to have been justified; this principle is described as "a common sense rule for doing good by preventing harm to public health by delay: when in doubt about the presence of a hazard, there should be no doubt about its prevention or removal." [30]

We believe that none of the non-causal explanations can account adequately for the consistent positive association across so many studies. Unfortunately, few studies were able to assess data pertaining to women with extreme exposure, such as those who applied talc directly to their perineum every day for decades. Nonetheless, the consistency of the overall results, combined with biological plausibility that talc acts, similarly to asbestos, as a carcinogen, persuades us that the use of talcum powder products can cause epithelial ovarian cancer in women who use it for feminine hygiene. Based on our review of the scientific and medical literature, it is our opinion that talcum powder products, including Johnson's Baby Powder and Shower to Shower, applied to the genital area of women, can cause ovarian cancer.

However, we reserve the right to amend this report should additional information become available or provided to us, and to review and comment on other legal expert reports.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Department of Epidemiology, Boston University School of Public Health

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EXHIBIT A

Curriculum Vitae of Bernard Harlow, PhD

CURRICULUM VITAE

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Education:

1975	B.S.	University of Rhode Island
1977	M.P.H.	University of Minnesota
1987	PH.D.	University of Washington

Professional Experience:

1987-1989	Instructor in Obstetrics, Gynecology and Reproductive Biology, Harvard Medical School, Boston, MA
1987-2005	Clinical Epidemiologist, Brigham and Women's Hospital Boston, MA
1989-1996	Assistant Professor of Obstetrics, Gynecology and Reproductive Biology, Harvard Medical School, Boston, MA
1990-2005	Co-Director, Obstetrics and Gynecology Epidemiology Center, Brigham and Women's Hospital, Boston, MA
1996-2005	Associate Professor of Obstetrics, Gynecology and Reproductive Biology, Harvard Medical School, Boston, MA
1999-2005	Associate Professor in the Department of Epidemiology, Harvard School of Public Health, Boston, MA
2005-2015	Mayo Professor, Division of Epidemiology and Community Health, University of Minnesota, Minneapolis, MN
2005-2014	Chair, Division of Epidemiology and Community Health, University of Minnesota, Minneapolis, MN

2005-2014	Adjunct Professor of Epidemiology, Harvard School of Public Health, Boston, MA
2006-2015	Adjunct Associate Professor, Department of Obstetrics, Gynecology and women's Health, University of Minnesota Medical School
2012-2015	Research Director, Building Interdisciplinary Research Careers in Women's Health (BIRWCH)
2013-2015	Associate Director, Populations and Community Engagement, Clinical and Translational Science Institute, University of Minnesota
2015-Present	Professor of Epidemiology. Boston University School of Public Health
2015-Present	Adjunct Mayo Professor, Division of Epidemiology and Community Health, University of Minnesota, Minneapolis, MN

Honors and Awards:

2003	Nominated for Mary Horrigan Connors Award for Outstanding Leadership in Women's Health, Brigham and Women's Hospital / Harvard Medical School
2004	Nominated for Mary Horrigan Connors Award for Outstanding Leadership in Women's Health, Brigham and Women's Hospital / Harvard Medical School
2005	Mayo Professor of Public Health, University of Minnesota School of Public Health
2011	Gaylord W. Anderson Leadership Award, University of Minnesota School of Public Health
2015-18	President-elect, President, Past-President, Society for Epidemiologic Research
2020	BUSPH Excellence in Research Mentoring Award

Governmental and External Committee Assignments

1999	Cancer Prevention Research Centers Grant Review Committee, Member, Center for Disease Control
2001	2001 Cancer Conference Planning Committee, Member, Center for Disease Control
2002-2005	Human Subjects Research Committee, Member, Brigham and Women's Hospital
2002-2005	Women's Health Advisory Council, Member, Pharmaceutical Industry Trade Organization
2002-2005	Education and Research Development Committee, Member, Brigham and Women's Hospital

2002	Cancer Prevention Research Centers Grant Review Committee, Member, Center for Disease Control
2004-2005	Expanding the Boundaries Funding Committee, Department of Obstet Gynecol, Member, Brigham and Women's Hospital
2004-Present	Scientific Advisory Board, Member, National Vulvodynia Association
2004	Quadrennial Site Visit Evaluation Committee for NICHD, Member, National Institutes of Health
2005	NIH-CSR Reproductive Epidemiology Study Section, Member, National Institutes of Health
2005-2006	Advisory Board of Connors Center for Women's Health & Gender Biology, Member, Brigham and Women's Hospital
2005	Special Emphasis Panel, Reproductive Health Research, Member, Center for Disease Control
2005-2006	Institute of Medicine National Research Council Committee on Assessing the Medical Risks of Human Oocyte Donation for Stem Cell Research
2006	NIH Infectious Disease, Reproductive Health, Asthma and Pulmonary (IRAP) Conditions Study Section
2008	Nominated as permanent member: NIH Infectious Disease, Reproductive Health, Asthma and Pulmonary (IRAP) Conditions Study Section
2009-2014	Member of the Board of Scientific Counselors for Clinical Sciences and Epidemiology of the National Cancer Institute
2011-2013	Chair, NIH Infectious Disease, Reproductive Health, Asthma and Pulmonary (IRAP) Conditions Study Section
2012-present	External Advisory Board, Boston Center for Endometriosis (BCE)
2014	External Advisory Committee, Department of Epidemiology, Brown University
2015 (Nov)	NIH-CSR– Chair, Ad-Hoc Study Section to review IRAP Study Section member grants.
2016 (July)	NIH-CSR – ECHO Data Coordinating Center Reviewer
2019 (Feb)	NIH – IRAP – Study Section Reviewer Grant Proposal Reviewer
2019 (June)	NIH-CSR – CKD- Coordinating Center Reviewer

2023 (Nov)	National Academies of Sciences, Engineering, and Medicine – Committee on Frameworks for the Consideration of Chronic Debilitating Conditions in Women.

University of Minnesota Committee Assignments

2006	Investigative Advisory Board for the National Children's Study: Ramsey Location being conducted by the University of Minnesota's School of Public Health
2006-2007	Chair, Search Committee for Head, Division of Biostatistics, School of Public Health, University of Minnesota
2007	Co-Chair, Search Committee for Health, Policy and Management Division Head, School of Public Health, University of Minnesota
2008	Search Committee: Chair of Department of Medicine, University of Minnesota Medical School
2008	Review Committee for the 2008 Academic Health Center Translational Research Grants
2009	Search Committee for the Academic Health Center Vice President for Research
1999-2005	Teaching commendations, Committee on Educational Policy, Harvard School of Public Health

Boston University Committee Assignments

2015-Present	Member: BU Clinical and Translational Science Institute's Strategic Executive Committee.
2015-2016	Co-Chair: Biostatistics, Epidemiology, Design and Analysis Center (BEDAC) Planning Committee.
2016-Present	DrPH Admissions and Monitoring Committee
2016	BU-CTSI Pilot Review Committee
2016-2017	Member, University Committee on Academic Program Review of BU
2016-2017	Member, MPH Admissions Committee
2018-2019	Co-Director, MS Degree Program in Epidemiology
2019-Present	Co-Director, MPH Epidemiology/Biostatistics Certificate Program
2020	BU-CTSI Pilot Review Committee

Editorial Service

1988-	Reviewer, Preventive Medicine
1992-	Reviewer, Epidemiology
1992-	Reviewer, Fertility & Sterility
1993-	Reviewer, American Journal of Public Health
1994-	Reviewer, American Journal of Obstetrics and Gynecology
1994-	Reviewer, Obstetrics and Gynecology
1995-	Reviewer, Journal of the National Cancer Institute
1995-	Reviewer, New England Journal of Medicine
1997-	Associate Editor, American Journal of Epidemiology
1998-	Reviewer, Maturitas
2000-	Reviewer, Paediatric & Perinatal Epidemiology
2002-	Reviewer, Journal of Epidemiology and Community Health
2002-	Reviewer, American Journal of Psychiatry
2002-	Reviewer, Archives of General Psychiatry
2003-	Reviewer, Obesity Research
2005-	Journal of Women's Health
2016-	British Journal of Gynecology and Obstetrics (BJOG)
2016-2017	Editor, Special 50th Anniversary Issue, American Journal of Epidemiology
2018-	Reviewer, Journal of Urology
2018-	Journal of the American Medical Association

Professional Societies:

1981-	Society for Epidemiologic Research, Member
1995-	American Public Health Association, Member
1997-	American College of Epidemiology, Peer-reviewed Fellow
2003-	International Society for the Study of Vulvovaginal Diseases, Peer-reviewed Fellow
2010-2013	Elected, Member-at-Large on Board of Directors of the Society for Epidemiological Research
2013-	American Epidemiological Society, elected to membership
2015-2017	President-Elect, President, Past President, Society for Epidemiological Research
2020-	Society for Perinatal Epidemiologic Research

B. Funding Information

Past

1987-1992	Project Director, N.I.H., NICHD/U01, Ultrasound screening in pregnancy
1989-1993	Co-P.I., N.I.H., NICHD/R01, Epidemiologic and biologic correlates of premature menopause;
1992-1993	Investigator, American Institute for Cancer Research, Galactose consumption and metabolism in familial ovarian cancer
1992-1997	Investigator, N.I.H., NCI/R01 , Ovarian cancer risk and hypergonadotropic hypogonadism

1994-1995	P.I., Milton Fund, Dietary Factors and Hyperemesis Gravidarum
1994-1998	Co-P.I., N.I.H., NICHD/R01, Epidemiologic and biologic predictors of IVF success
1995-2000	P.I., N.I.H., R01-HD50013, Depression and Hypogonadism
1998-2000	Project Director, N.I.H., NIMH/R01, Epidemiology of Ovarian Function in relation to violence
1998-2000	P.I., Partners Women's Cancer Collaborative Research, Pathogenesis and Prevention of Cervical Cancer
1998-2002	Investigator, N.I.H., R01-HD, Epidemiologic and biologic predictors of IVF success
1998-2003	Investigator, N.I.H., R01-CA, Ovarian cancer risk and hypergonadotropic hypogonadism
1999-2003	P.I. (Subcontract), N.I.H., R01-MH, Relapse of Depression during Pregnancy and Puerperum
2000-2005	P.I., N.I.H., R01-HD, Prevalence and etiological predictors of vulvodynia
2003-2005	P.I., National Alliance for Research on Schizophrenia and Depression, Postpartum psychosis in women with prior psychiatric hospitalizations
2003-2006	P.I. (Subcontract), N.I.H., R01-MH, Predictors of antenatal and postpartum depression
2003-2008	P.I. (Subcontract), N.I.H., R01-MH, Risk and Predictors of Postpartum Depression
2004-2006	P.I. N.I.H., R01-HD, Risk for new onset of depression in perimenopausal women
2006- 2009	P.I. (Subcontract) N.I.H., R01-HD, Risk for new onset of depression in perimenopausal women
2007-2008	P.I. University of Minnesota, Office of International Programs, Interdisciplinary and Intercultural Public Health and Medical Program in Ecuador
2008-2009	P.I. University of Minnesota, Office of International Programs, Interdisciplinary and Intercultural Public Health and Medical Program in Ecuador
2009-2014	P.I. N.I.H., R01-HD058608-01A1, Immunological Factors and Risk of Vulvodynia
2012-2017	Co-I (Raymond PI) University of Minnesota Building Inter-Disciplinary Careers in Women's Health Program (BIRWCH). **Direct Costs: $462,956**.
2011-2015	Co-I (Blazer PI) NIH-NCATS UL1TR000114, University of Minnesota Clinical and Translational Sciences Award. **Direct Costs: $34,855,966**

2016-2017 P.I. – NIH-NCATS - 1 R13 TR002021-01 – SER Doctoral Student Workshop.
Direct Costs: $18,000

2017-2018 P.I. – NIH-NCATS - 1 R13 TR002021-02 – SER Doctoral Student Workshop.
Direct Costs: $28,000

2017-2018 Co-PI National Vulvodynia Association – Molecular Microbial Markers and Vulvodynia
Direct Costs: $20,000

2017-2018 P.I. – Neonatal exposures and subsequent risk of vulvodynia – A lifecourse analysis for exploring immune dysfunction
Direct Costs: $20,000

2019-2020 P.I. – BUSPH Pilot Grant - Vulvar Pain Assessment Questionnaire (VPAQ) – Feasibility Assessment within a College Student Population.
Direct Costs: $20,000

2020-2021 P.I. – BUSPH Pilot Grant - Boston STRONG (Study to Tackle Risks Of iNcontinence post-Gestation) – Feasibility Assessment Within a Pregnant and Postpartum Population.
Direct Costs: $15,000 (in conjunction with $15,000 from BMC)

Current

2020-2025 P.I. NIH 1-U24 DK106786-06, Prevention of Lower Urinary Tract Symptoms in Women: Bladder Health Scientific and Data Coordinating Center (PLUS-SDCC)
Direct Costs: $2,000,000

2017-2022 PI-Subcontract (Robinson PI) NIH-NICHD 1-R01 HD - Sexual pain and genital cutting among Somali women in Minnesota
Direct Costs: $46,812

2020-2022 P.I. – NIH-R21 HD099533-01: Risk of vulvodynia due to immune-related health events throughout the life course
Direct Costs: $229,720

Pending

2023-2025 MPI – NIH-R21 HD111728-01: A North American preconception cohort study of the vaginal microbiome, subfertility, and miscarriage
Direct Costs: $229,720

Teaching:

Year	**Class Title**	**# of Students**
1990	Resident and Fellow Independent Mentorship	5

1999-2005	HSPH-EPI269-Epidemiologic Research in Obstetrics and Gynecology	20
2001-2005	HSPH-EPI270-Advanced Topics in Reproductive Epidemiology	8
2003-2005	HSPH-EPI287-Female Reproductive Morbidity Associated With Trauma and Stress	15
2003-2005	Epidemiologic Research Methods for Ob/Gyn Residents and Fellows	20
Spr 2005-2011	PubH 8377 Seminar: Chronic Disease and Behavioral Epidemiology	10-15
Fall 2006-2011	PubH 6348 Writing Research Grants	10-15
Winter 2005-2011	Winter Short Course, Harvard School of Public Health: Bridging Psychiatric Morbidity and Adverse Reproductive Outcomes.	
Summer 2006	PubH 6600 Women's Mental Health and Reproductive Outcomes	
Fall 2012-2013	PubH 6341 Epidemiologic Methods I	60
Spring 2017	EP 813 Intermediate Epidemiology	25
Fall 2017	EP 722 Data Collection Methods for Epidemiologic Research	16
Summer 2018	EP 722 Data Collection Methods for Epidemiologic Research	9
Fall 2018	EP 722 Data Collection Methods for Epidemiologic Research	18
Spring 2019	EP 817 Guided Epidemiologic Research	8
Summer 2019	EP 722 Data Collection Methods for Epidemiologic Research	10
Fall 2019	EP 722 Data Collection Methods for Epidemiologic Research	20
Spring 2020	EP 817 Guided Epidemiologic Research	12
Summer 2020	EP 722 Data Collection Methods for Epidemiologic Research	10
Fall 2020	EP 816 Guided Epidemiologic Research	9
Fall 2020	EP 722 Data Collection Methods for Epidemiologic Research	24
Fall 2020	Development of New Asynchronous Data Collection Methods Course	
Spring 2021	PH 880 Guided Epidemiologic Research (Continuation)	
Spring 2021	EP 722 Data Collection Methods for Epidemiologic Research (Asynchronous)	
Spring 2022	EP 722 Data Collection Methods for Epidemiologic Research (Asynchronous)	
Fall 2022	EP 816 Guided Epidemiologic Research	11

Advisees/Trainees - Research

Training Duration	Name	Current Position
1992-1993	Carolyn Zelop, M.D.	Ultrasonographer, Chicago Lying-In Hospital
1995-1997	Sarah Feldman, M.D., MPH	Assistant Professor
1996-1997	Isaac Glatstein, M.D.	Reproductive Endocrinologist, Private Practice
1996-1999	Lisa B. Signorello, Ph.D.	Senior Epidemiologist, International Epidemiology Association, Associate Professor, Harvard SPH
1998-1999	Ramin Mirhashemi, M.D.	Gyn Oncologist, University of Miami
1998-2003	Lauren A. Wise, Sc.D.	Associate Professor, Slone Epidemiology Center, Boston University
2000-2001	Les Reti, M.D., MPH	Gynecologic Oncologist, Private Practice
2000-2003	Beth Bazydlo, MS	Research Associate, Abt Associates
2001-2003	Hazel Bogan, MS	Research Associate, University of Wisconsin, Madison
2001-2003	Hadine Joffe, M.D., MS	Assistant Professor, Perinatal Psychiatry, Mass General Hospital
2001-2004	Geetanjali Datta, MS	Research Associate, Slone Epidemiology Unit, Boston University

2001-2004	Sara Cherkerzian, Sc.D.	Postdoctoral Fellow, Psychiatric Epidemiology
2003-2005	Elizabeth Reed, MS	Doctoral Student, HSPH
2003-2005	Michele Hacker, MS	Doctoral Student, HSPH
2004-2005	Haim A. Abenhaim, M.D.	Resident, Ob/Gyn, McGill University
2004-2005	Ghasi Phillips, MS	Doctoral Student, HSPH
2006-2008	Bassim Birkland, MS	Epidemiology, MPH
2006-2009	Erin Galegher, MPH	Epidemiology, MPH
2006-2009	Trista Olmstead,	Maternal & Child Health, MPH
2007-2009	Jennifer (Springsteen) Fricton	Maternal & Child Health, MPH
2007-2009	Katy Backes Kozhimannil	Assistant Professor, HPM, UMN
2008-2010	Roma Patel	Epidemiology, MPH
2009-current	Maheruh Khandker	Epidemiology, PhD
2010-2014	Laura Anderson	Maternal & Child Health, MPH
2011-2014	Christine Kunitz	Epidemiology, PhD
2011-2014	Alyssa Herreid	Epidemiology, MPH
2016-	Miriam Haviland	Epidemiology, PhD
2017-	Sam Golenbach	Epidemiology MS
2017-	Ying Sun	Epidemiology MPH
2017-	Lisa Bedford	Epidemiology MS
2018-	Sydney Willis	Epidemiology PhD
2019-	Julia C Bond	Epidemiology PhD
2020-2022	Chad M Coleman	Epidemiology PhD
2022-	Amy Zheng	Epidemiology PhD

Invited Presentations:

1981 Telephone Interviewing Methods, National Institutes of Health

1982 Assessing Occupational Exposures, National Institute for Occupational Safety and Health

1983 Telephone Household Screening and Interviewing, Fred Hutchinson Cancer Research Center

1984 A Comparison of Computer Assisted and Hard Copy Telephone Interviewing, University of Washington, Seattle, WA

1986 Health Services Research Methods Course, University of Washington, Seattle, WA

1987 The Influence of Perineal Exposure to Talc on the Risk of Borderline Ovarian Tumors, Society for Epidemiologic Research

1987 Epidemiology of Borderline Ovarian Tumors, University of Washington

1990 The Influence of Lactose Consumption on the Association of Oral Contraceptives and Ovarian Cancer Risk, Fred Hutchinson Cancer Research Center

1990 The Influence of Lactose Consumption on the Association of Oral Contraceptives and Ovarian Cancer Risk, University of Minnesota

1992 Depression and Hypogonadism, Society for Epidemiologic Research Annual Meeting

1993 Talc: Consumer Uses and Health Perspectives, FDA Workshop, NIH

1994 The Relationship Between Depression and Ovarian Function: An Epidemiological Perspective, Dartmouth Medical School

1994 The Relationship Between Depression and Ovarian Function: An Epidemiological Perspective, Yale University School of Public Health

1994 Physical Activity and Risk of Early Menopause, Society for Epidemiologic Research Annual Meeting

1995 Self-reported use of antidepressants and benzodiazepine tranquilizers and risk of epithelial ovarian cancer, American Association for Cancer Research Annual Meeting

1996 Assessing major depression and ovarian function: Results from the Harvard Study of Moods and Cycles, American Psychiatric Association Annual Meeting

1996 Harvard Study of Moods and Cycles: Depression and factors related to menstruation and ovulation, Society for Epidemiologic Research Annual Meeting

1996 Reproductive correlates of chronic fatigue syndrome, American Public Health Association Annual Meeting

1997 Use of psychotropic medication and risk of malignant epithelial ovarian cancer, American College of Epidemiology Annual Meeting

1997 Integration of biological, clinical, and epidemiological data in the assessment of ovarian cancer and other disorders in women, Dartmouth Medical School

1997 Influence of major depression on reproductive function: Preliminary results from the Harvard Study of Moods and Cycles, Department of Family and Community Medicine, Brown Medical School

1998 Epidemiology of Ovarian Cancer, Dana Farber Cancer Institute

1999 Reproductive endocrine correlates of major depression: Results from the Harvard Study of Moods and Cycles, International Epidemiology Association

2000 The influence of depression on ovarian function: Results from the Harvard Study of Moods and Cycles, Women's Health 2000 Conference

2001 Cervical Cancer Etiology and HPV Infection, CDC

2001 Prevalence and Predictors of Chronic Lower Genital Tract Discomfort, Female Sexual Function Forum

2001 Major depression and the risk of an early transition to the menopause: Results from the Harvard Study of Moods and Cycles, National Institutes of Health

2002 Depression and the Transition to the Perimenopause: The Harvard Study of Moods and Cycles, American Psychiatric Association

2002 Depression and Perimenopause: Results from the Harvard Study of Moods and Cycles, Oxford University, Institute of Health Sciences

2002 Chronic Unexplained Vulvar Pain: Is vulvar dysesthesia a silent epidemic?, Oxford University, Department of Ob/Gyn

2002 Prevalence and Etiologic Predictors of Chronic Lower Genital Disorders: Are we facing a silent epidemic? NICHD, National Institutes of Health

2003 Depression and Risk of Early Perimenopause, Dept of Medical Epidemiology, Karolinska Institutet, Stockholm, Sweden

2003 NIH Study Prevalence and Etiology of Vulvodynia, Dandryd Hospital, Karolinska Institutet, Stockholm, Sweden

2003 NIH Conference on Vulvodynia - Toward Understanding a Pain Syndrome, National Institutes of Health

2004 Vulvodynia and sexual pain disorders in women: A state of the art consensus conference, National Institutes of Health

2004 Prevalence and Etiological Predictors of Vulvodynia, Society for Sex Therapy and Research, Annual Meeting, Washington DC

2004 Prevalence and Etiological Predictors of Vulvodynia, American Medical Women's Association Annual Meeting

2004 Depression and Perimenopause: The Harvard Study of Moods and Cycles, Department of Epidemiology, McGill University

2006 Understanding The Bridge Between Reproductive Morbidity and Psychiatric Disorders. 2006 Congress of Epidemiology Meeting

2006 Influence of Mood Disorders on The Early Onset of Menopause. Obstetrics Gynecology Grand Rounds, University of Minnesota Medical School

2007 Assessment of Clinical and Epidemiological Markers Related to Altered Immuno-Inflammatory Response Among Women With and Without Vulvodynia. International Society for the Study of Vulvovaginal Disease Word Congress, Alaska, July 28-August 4, 2007

2007 Global Women's Health Update: An epidemiological perspective. Obstetrics, Gynecology, & Women's Health: 38th Annual Autumn Seminar, October 1-2, 2007, Minneapolis, Minnesota

2008 Harvard Study of Moods and Cycles. Department of OBGYN Grand Rounds, Iceland Women's Hospital, Reykjavik, Iceland

2008 Etiology of Vulvodynia. Iceland Society of Obstetrics and Gynecology, Reykjavik, Iceland

2008 New Insight Into The Etiology of Vulvodynia. Guest Speaker: Resident and Fellow Research Day, Minneapolis, Minnesota, May 12, 2008

2008 NIH Study Prevalence And Etiology of Vulvodynia, Dandryd Hospital, Karolinska Institute, Stockholm, Sweden

2008 Menopause & Depression: Is There a Link? North American Menopause Society National Meeting, Orlando, Florida (Sept)

2008 Exploring the Etiology of Vulvodynia: An Unexplained Vulvar Pain Syndrome. University of Washington, Seattle, Washington (Nov)

2010 Probing the Pathogenesis of Unexplained Vulvar Pain. Lecture at the University of Vermont, Burlington Vermont (January)

2010 Probing the Pathogenesis of Unexplained Vulvar Pain. OB/GYN Grand Rounds, Mayo Clinic, Rochester, Minnesota (April)

2010 Probing the Pathogenesis of Unexplained Vulvar Pain. University of Minnesota, School of Public Health, Mayo Lecture (October)

2012 Geographic variation in new onset depression during the menopausal transition: can we believe our data? New Findings from the Harvard Study of Moods and Cycles. Columbia University (March)

2012 Disparate rates of new onset depression during the menopausal transition: Biased or real? 9th Annual Women's Health Research Conference, Minneapolis, MN (Sept)

2013 Vulvodynia: Prevalent, Debilitating, Poorly Understood; Environmental and Psychiatric Immunoinflammatory Hypotheses. Royal Women's Hospital, Melbourne, Australia (January)

2013 Vulvodynia: Prevalent, Debilitating, Poorly Understood; Environmental and Psychiatric Immunoinflammatory Hypotheses. James Cook University School of Public Health (February)

2013 Vulvodynia: Prevalent, Debilitating, Poorly Understood; Environmental and Psychiatric Immunoinflammatory Hypotheses. NICHD Program in Reproductive and Adult Endocrinology Research Conference. (April)

2014 Vulvodynia: Prevalent, Debilitating, Poorly Understood; Exploring Biopsychosocial Hypotheses. Harvard School of Public Health Invited Seminar Series (October)

2014 Vulvodynia: Prevalent, Debilitating, Poorly Understood; Exploring Biopsychosocial Hypotheses. Medical University of South Carolina Seminar (November)

2015 The role of trauma and psychiatric morbidity in women's gynecological disorders. Harvard T.H. Chan School of Public Health, Psychiatric Epidemiology Colloquium. (December)

2016 Recurrent Yeast Infections and Vulvodynia: Can we believe associations based on self-reported data? American Epidemiological Society (March)

2016 Vulvodynia: Prevalent, Debilitating, Poorly Understood; Exploring Biopsychosocial Hypotheses. University of Massachusetts School of Public Health Invited Seminar (April)

2017 The Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium: *A transdisciplinary approach toward promoting bladder health and preventing lower urinary tract symptoms in women across the life course.* University of Iceland, Department of Public Health Sciences (September)

2018 The association of vulvodynia and urological urgency and frequency: Findings from a community-based study. The International Continence Society Annual Meeting. Philadelphia, August, 2018.

2019 Vaginal microbiome and vulvodynia. International Society for the Study of Vulvovaginal Diseases (ISSVD World Congress, Turin, Italy. (September)

2020 Lower Urinary Tract Symptoms at Age 19: Associations with Sexual Activities Prior to Age 17. American Urogynecology Society (September)

2020 Invited Symposium: Vulvodynia: Prevalent; Debilitating; An Epidemiologic Challenge. Society for Perinatal Epidemiologic Research (December)

2022 Invited Symposium: Vulvodynia: Prevalent; Debilitating; An Epidemiologic Challenge. International Society for the Study of Vulvovaginal Diseases (ISSVD World Congress, Dublin, Ireland. (June)

Publications

Reviews/Chapters/Editorials

1. **Harlow BL**, Hartge PA. A review of perineal talc exposure and risk of ovarian cancer. Regul Toxicol Pharmacol. 1995;21(2):254-60.
2. **Harlow BL**, Abraham ME. Depression in Menopause. In: Seifer DB, Kennard EA, editors. Menopause: Endocrinology and Management. Totowa (NJ): The Humana Press, Inc; 1999. p. 111-124.

3. Gyllstrom ME, Schreiner PJ, **Harlow BL**. Pereimenopause and depression: strength of association, causal mechanisms and treatment recommendations. Chapter 8 in: Best Practice & Research Clinical Obstetrics and Gynaecology, Vol 21, No. 2, pp. 275-292, 2007.
4. Ferguson S, Soares CN, **Harlow BL**. Depression during the Perimenopausal Transition: What have we learned from epidemiological studies? In: Soares C, Warren M (eds): The Menopausal Transition. Interface between Gynecology and Psychiatry. Key Issues in Mental Health. Basel, Karger, 2009, vol 175, pp 66-76.
5. Rasmussen-Torvik, LJ and **Harlow BL.** The association between depression and diabetes in the perinatal period. Curr Diab Rep 2010; 10(3):217-23.
6. **Harlow BL**, Khandker M, Stewart EG, Margesson LJ. Vulvodynia. Chapter 24 In: Goldman MB and Hatch MC (eds): Women & Health, 2nd edition.
7. **Harlow BL,** Haviland MJ, Bergeron S. Vulvodynia and Psychiatric Comorbidities. Chapter 25 In: Maldonado-Bouchard S, Clark MR, Incayawar M (Eds): Overlapping Pain and Psychiatric Syndromes. Oxford University Press, In Press.
8. **Harlow BL,** Szklo M. Editorial: The 50th Anniversary of the Society for Epidemiologic Research. Am J Epidemiol 2017;185:988-989.

Original Articles

1. **Harlow BL**, Hartge P. Telephone household screening and interviewing. Am J Epidemiol. 1983;117(5):632-3.
2. **Harlow BL**, Rosenthal JF, Ziegler RG. A comparison of computer-assisted and hard copy telephone interviewing. Am J Epidemiol. 1985;122(2):335-40.
3. **Harlow BL**, Weiss NS, Lofton S. The epidemiology of sarcomas of the uterus. J Natl Cancer Inst. 1986;76(3):399-402.
4. Voigt LF, **Harlow BL**, Weiss NS. The influence of age at first birth and parity on ovarian cancer risk. Am J Epidemiol. 1986;124(3):490-1.
5. Weiss NS, **Harlow BL**. Why does hysterectomy without bilateral oophorectomy influence the subsequent incidence of ovarian cancer? Am J Epidemiol. 1986;124(5):856-8.
6. **Harlow BL**, Weiss NS, Lofton S. Epidemiology of borderline ovarian tumors. J Natl Cancer Inst. 1987;78(1):71-4.
7. **Harlow BL**, Davis S. Two one-step methods for household screening and interviewing using random digit dialing. Am J Epidemiol. 1988;127(4):857-63.
8. **Harlow BL**, Weiss NS, Roth GJ, Chu J, Daling JR. Case-control study of borderline ovarian tumors: reproductive history and exposure to exogenous female hormones. Cancer Res. 1988;48(20):5849-52.
9. Cramer DW, **Harlow B**L, Barbieri RL, Ng WG. Galactose-1-phosphate uridyl transferase activity associated with age at menopause and reproductive history. Fertil Steril. 1989;51(4):609-15.
10. Saltzman DH, Frigoletto FD, **Harlow BL**, Barss VA, Benacerraf BR. Sonographic evaluation of hydrops fetalis. Obstet Gynecol. 1989;74(1):106-11.
11. Cramer DW, **Harlow BL**, Willett WC, Welch WR, Bell DA, Scully RE, Ng WG, Knapp RC. Galactose consumption and metabolism in relation to the risk of ovarian cancer. Lancet. 1989;2(8654):66-71.
12. **Harlow BL**, Weiss NS. A case-control study of borderline ovarian tumors: the influence of perineal exposure to talc. Am J Epidemiol. 1989;130(2):390-4.
13. **Harlow BL**, Weiss NS. Re: "Familial ovarian cancer: a population-based case-control study". Am J Epidemiol. 1989;130(5):1071-3.

14. Benacerraf BR, Mandell J, Estroff JA, **Harlow BL**, Frigoletto FD. Fetal pyelectasis: a possible association with Down syndrome. Obstet Gynecol. 1990;76(1):58-60.
15. Benacerraf BR, **Harlow BL**, Frigoletto FD. Hypoplasia of the middle phalanx of the fifth digit. A feature of the second trimester fetus with Down's syndrome. J Ultrasound Med. 1990;9(7):389-94.
16. **Harlow BL**, Weiss NS, Holmes EH. Plasma alpha-L-fucosidase activity and the risk of borderline epithelial ovarian tumors. Cancer Res. 1990;50(15):4702-3.
17. Benacerraf BR, **Harlow B**, Frigoletto FD Jr. Are choroids plexus cysts an indication for second-trimester amniocentesis? American Journal of Obstetrics & Gynecology 1990;162(4):1001-6.
18. Bromley B, **Harlow BL**, Laboda LA, Benacerraf BR. Small sac size in the first trimester: a predictor of poor fetal outcome. Radiology. 1991;178(2):375-7.
19. **Harlow BL**, Cramer DW, Geller J, Willett WC, Bell DA, Welch WR. The influence of lactose consumption on the association of oral contraceptive use and ovarian cancer risk. Am J Epidemiol. 1991;134(5):445-53.
20. Cramer DW, **Harlow BL**. Commentary: re: "A case-control study of milk drinking and ovarian cancer risk." Am J Epidemiol. 1991;134(5):454-6.
21. de Haas I, **Harlow BL**, Cramer DW, Frigoletto FD. Spontaneous preterm birth: a case-control study. Am J Obstet Gynecol. 1991;165(5 Pt 1):1290-6.
22. Hill JA, Polgar K, **Harlow BL**, Anderson DJ. Evidence of embryo- and trophoblast-toxic cellular immune response(s) in women with recurrent spontaneous abortion. Am J Obstet Gynecol. 1992;166(4):1044-52.
23. **Harlow BL,** Cramer DW, Bell DA, Welch WR. Perineal exposure to talc and ovarian cancer risk. Obstet Gynecol. 1992;80(1):19-26.
24. Goodman HM, **Harlow BL**, Sheets EE, Muto MG, Brooks S, Steller M, Knapp RC, Berkowitz RS. The role of cytoreductive surgery in the management of stage IV epithelial ovarian carcinoma. Gynecol Oncol. 1992;46(3):367-71.
25. Zelop CM, **Harlow BL**, Frigoletto FD, Safon LE, Saltzman DH. Emergency peripartum hysterectomy. Am J Obstet Gynecol. 1993;168(5):1443-8.
26. **Harlow BL**, Crea EC, East MA, Oleson B, Fraer CJ, Cramer DW. Telephone answering machines: the influence of leaving messages on telephone interviewing response rates. Epidemiology. 1993;4(4):380-3.
27. **Harlow BL**, Fuhr JE, McDonald TW, Schwartz SM, Beuerlein FJ, Weiss NS. Flow cytometry as a prognostic indicator in women with borderline epithelial ovarian tumors. Gynecol Oncol. 1993;50(3):305-9.
28. Muto MG, Cramer DW, Brown DL, Welch WR, **Harlow BL**, Xu H, Brucks JP, Tsao SW, Berkowitz RS. Screening for ovarian cancer: the preliminary experience of a familial ovarian cancer center. Gynecol Oncol. 1993;51(1):12-20.
29. Bromley B, Frigoletto FD, **Harlow BL**, Evans JK, Benacerraf BR. Biometric measurements in fetuses of different race and gender. Ultrasound Obstet Gynecol. 1993;3(6):395-402.
30. Cramer DW, Barbieri RL, Muto MG, Kelly A, Brucks JP, **Harlow BL**. Characteristics of women with a family history of ovarian cancer. II. Follicular phase hormone levels. Cancer. 1994;74(4):1318-22.
31. Bromley B, Frigoletto FD, **Harlow BL**, Pauker S, Benacerraf BR. The role of Doppler velocimetry in the structurally normal second-trimester fetus with elevated levels of maternal serum alpha-fetoprotein. Ultrasound Obstet Gynecol. 1994;4(5):377-80.
32. Spirtas R, Heineman EF, Bernstein L, Beebe GW, Keehn RJ, Stark A, **Harlow BL**, Benichou J. Malignant mesothelioma: attributable risk of asbestos exposure. Occup Environ Med. 1994;51(12):804-11.

33. **Harlow BL**, Frigoletto FD, Cramer DW, Evans JK, Bain RP, Ewigman B, McNellis D. Epidemiologic predictors of cesarean section in nulliparous patients at low risk. RADIUS Study Group. Routine Antenatal Diagnostic Imaging with Ultrasound Study. Am J Obstet Gynecol. 1995;172(1 Pt 1):156-62.
34. Cramer DW, Xu H, **Harlow BL**. Does "incessant" ovulation increase risk for early menopause? Am J Obstet Gynecol. 1995;172(2 Pt 1):568-73.
35. Feldman S, Cook EF, **Harlow BL**, Berkowitz RS. Predicting endometrial cancer among older women who present with abnormal vaginal bleeding. Gynecol Oncol. 1995;56(3):376-81.
36. **Harlow BL**, Cramer DW. Self-reported use of antidepressants or benzodiazepine tranquilizers and risk of epithelial ovarian cancer: evidence from two combined case-control studies (Massachusetts, United States). Cancer Causes Control. 1995;6(2):130-4.
37. Hornstein MD, **Harlow BL**, Thomas PP, Check JH. Use of a new CA 125 assay in the diagnosis of endometriosis. Hum Reprod. 1995;10(4):932-4.
38. **Harlow BL**, Cramer DW, Annis KM. Association of medically treated depression and age at natural menopause. Am J Epidemiol. 1995;141(12):1170-76.
39. Cramer DW, **Harlow BL**, Xu H, Fraer C, Barbieri R. Cross-sectional and case-controlled analyses of the association between smoking and early menopause. Maturitas. 1995;22(2):79-87.
40. Berkowitz RS, Bernstein MR, **Harlow BL**, Rice LW, Lage JM, Goldstein DP, Cramer DW. Case-control study of risk factors for partial molar pregnancy. Am J Obstet Gynecol. 1995;173(3 Pt 1):788-94.
41. Cramer DW, Xu H, **Harlow BL**. Family history as a predictor of early menopause. Fertil Steril. 1995;64(4):740-5.
42. **Harlow BL**. Coping with the personal and professional frustrations of epidemiologic research. Am J Epidemiol. 1995;142(8):785-7.
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162. Danish AN, Mason SM, Brady SS, **Harlow BL**. Vulvodynia and Social Support. Pain Med 2021; In review
163. James AS, ……**Harlow BL**. Building Community Engagement capacity in a transdisciplinary, population health research consortia, In press.
164. Husain J,….**Harlow BL** The Effect of Cannabis Use on Opioid Relapse in Patients on Extended-Release Naltrexone or Buprenorphine-Naloxone for Opioid Use Disorder: A Secondary Analysis of the X:BOT Trial. Amer J Addictions, In press.
165. Raposa M, Smithers DL, Matthews CM, **Harlow BL**. Depression and help seeking behaviors among college students: Findings from the Healthy Minds Study. J American College Health, In press.
166. Yang Y, Valdimarsdottir UA, Manson JE, Sievert LL Harlow BL, Eliassen AH, Bertone-Johnson ER, Lu D. Premenstrual disorders, timing of menopause and severity of vasomotor symptoms. 10.1001/jamanetworkopen.2023.34545

EXHIBIT B

Curriculum Vitae of Kenneth Rothman, DrPH

Curriculum Vitae of Kenneth Jay Rothman

Academic Training

Dr.P.H.	Epidemiology and Biostatistics Harvard School of Public Health	1972
M.P.H.	Epidemiology Harvard School of Public Health	1970
D.M.D.	Dental Medicine Harvard School of Dental Medicine	1969
A.B.	Physical Sciences Colgate University	1966

Honors

Phi Beta Kappa; Student Prize Paper, Society for Epidemiologic Research, 1972; Adolph G. Kammer Award, American Occupational Medical Association, 1983; James H. Sterner Lecturer, University of California at Irvine, 1987; Boston University School of Public Health Excellence in Teaching Award, 1990, 1991, 1992, 1996; American Journal of Epidemiology “Classic Paper” selection ("Causes," originally published in 1976), 1995; Will Solimene Award for Excellence in Medical Communication, American Medical Writers Association, 1997; Honorary Fellowship, American College of Epidemiology, 1997; Commencement Speaker, Netherlands Institute for Health Science, Erasmus University, Rotterdam, June 1999; American Public Health Association Lilienfeld Teaching Award, 2000; Fellowship, International Society for Pharmacoepidemiology, 2005; Distinguished Fellow, RTI International, 2008; Harry Guess Memorial Lecture, UNC Gillings School of Public Health, 2009; Mildred Morehead Visiting Professor and Lecturer, Albert Einstein College of Medicine, 2010; Saward-Berg Invited Lecturer, University of Rochester, 2012; Leonard M. Schuman Invited Lecture, University of Michigan, 2012; Abraham Lilienfeld Award for Excellence in Epidemiology, American College of Epidemiology, 2014; Cutter Lecturer, Harvard University School of Public Health, 2014; Harland Austin Invited Lecturer, Emory University School of Public Health, 2015; Society for Epidemiologic Research Career Accomplishment Award, 2017; Honorary Degree: M.D. *Honoris Causa*, Univ of Aarhus, 2017; Honorary Skou Professor of Epidemiology, Univ of Aarhus, 2019-24.

Positions Held

Position	Institution	Dates
Distinguished Fellow Emeritus	Research Triangle Institute	2022-Present
Professor	Department of Epidemiology Boston University School of Public Health	1988-Present
Honorary Professor	Department of Clinical Epidemiology Faculty of Health, Aarhus University	2012-Present

Distinguished Fellow	Research Triangle Institute	2009-2021
VP Epidemiology	RTI Health Solutions	2005-2021
Foreign Adjunct Professor	Department of Medical Epidemiology Karolinska Institute, Stockholm	2001-2006
Adjunct Professor	Department of Epidemiology Harvard School of Public Health	1992-2006
Founding Editor	*Epidemiology*	1988-2001
Senior Scientist	Epidemiology Resources Inc. Newton Lower Falls, MA	1980-1999
Professor	Department of Family and Community Medicine U. of Mass. Medical School	1984-1989
Consultant in Epidemiology	Massachusetts General Hospital Boston, MA	1975-1985
Research Associate in Cardiology	Children's Hospital Boston, MA	1973-1985
Associate Professor	Department of Epidemiology Harvard School of Public Health	1975-1984
Visiting Epidemiologist	National Cancer Institute Bethesda, MD	1976-1977
Assistant Professor	Department of Epidemiology Harvard School of Public Health	1972-1975

Other Professional Activities

Member	Editorial Board, Eur J Epidemiol	2011-Present
Member	Editorial Board, RTI Press	2015-2021
Member	Scientific Advisory Board, Observational Medical Outcomes Partnership (OMOP), Foundation For the National Institutes of Health	2009-2013
Board of Directors	Intl. Society for Pharmacoepidemiology	2002-2008

Member	International Agency for Research on Cancer (IARC) Review Committee Biostatistics and Epidemiology	2007
Member	Board of Scientific and Policy Advisers American Council on Science and Health	1988-2006
Member	Scientific Oversight Committee Interphone Study International Union Against Cancer	2002-2006
Member	CDC/IOM Workshop on the Health Burden of Overweight and Obesity	2006
Member	External Epidemiology Advisory Panel National Institute of Allergy and Infectious Disease	2005
International Advisory Board	*The Lancet*	1996-2002
Member	National Council on Radiation Protection and Measurements, Scientific Committee 59 (Evaluation of Human Irradiation Exposure Experience)	1979-1992
Chair	Working Group on Methodology Issues in Environmental Epidemiology The Health Effects Institute	1990-1992
Editorial Board	*New England Journal of Medicine*	1978-1989
Member	Health and Environment Research Advisory Committee U.S. Department of Energy	1986-1989
Editor	*American Journal of Epidemiology*	1982-1987
Assistant Editor	*American Journal of Public Health*	1983-1987
Board of Overseers	*American Journal of Epidemiology*	1984-1985
President	Society for Epidemiologic Research	1984-1985

Epidemiology Section Council	American Public Health Association	1979-1985
Member	Advisory Committee to the Surgeon General on the Health Consequences of Smokeless Tobacco	1984-1985
Co-chair	Advisory Panel Consensus Workshop on Formaldehyde Environmental Protection Agency and National Center for Toxicological Research (Environmental Health Perspectives, Vol. 58, Dec. 1984)	1983
Associate Editor	*American Journal of Epidemiology*	1979-1982

Invited Courses in Epidemiologic Methods

Erasmus Summer Programme	2002-2017 (annually)
Erasmus Winter Programme	2009-2018 (annually)
Universitá Cattolica del Sacro Cuore, Rome	2007, 09, 11, 13, 15, 17
Teikyo University, Tokyo, Japan	2014
Australian Res. Allian. for Children & Youth	2013
University of Auckland, New Zealand	2008
University of Halle, Germany	2005
Ohio State University	2002, 2004
Nat. Inst. Publ. Hlth (RIVM), The Netherlands	2001, 2002
Mediterranean School of Epidemiology	2001
Free University, The Netherlands	1998
University of Tasmania, Australia	1995, 1997, 2002, 2006
California Department of Health Services	1994
University of Uppsala, Sweden	1993
University of Madrid, Spain	1993
University of Santiago de Compostela, Spain	1991
University of Oslo, Norway	1990, 2005, 09, 12, 14
University of Nijmegen, The Netherlands	1989, 91, 94, 95, 97, 2000, 2002
Bundesgesundheitsamt, Germany	1988
U. S. Food and Drug Administration, DHHS	1988
University of Utah	1987
University of Aarhus, Denmark	1986, 92, 94, 96, 2003
Karolinska Institute, Sweden	1981, 83, 85, 87, 2002
New England Epidemiology Institute	1981-2001 (annually)
Massachusetts Institute of Technology	1980, 81
Centers for Disease Control	1979, 81
University of Washington	1978, 80, 85

University of North Carolina	1977
University of Minnesota	1974, 1975, 1976

Books

Epidemiologic Analysis with a Programmable Calculator. **Rothman KJ** and JD Boice Jr., U.S. Department of Health, Education and Welfare, Public Health Service, National Institutes of Health, NIH Publication No. 79-1649, 1979.

Epidemiologic Analysis with a Programmable Calculator, with an Appendix for the HP-41CV by H Austin. **Rothman KJ** and JD Boice Jr., Epidemiology Resources Inc., Boston, MA, 1982.

Modern Epidemiology. **Rothman KJ**. Little, Brown & Co., Boston, MA, 1986.

Causal Inference. **Rothman KJ**, ed. Epidemiology Resources Inc., Boston, MA, 1988.

Modern Epidemiology, 2nd Edition. **Rothman KJ** and Greenland S. Lippincott, Philadelphia, PA, 1998

Epidemiology. An Introduction. **Rothman KJ**. Oxford University Press, New York, 2002

Modern Epidemiology, 3rd Edition. **Rothman KJ,** Greenland S and Lash T. Lippincott, Philadelphia, PA, 2008

Epidemiology. An Introduction, 2nd Edition. **Rothman KJ**. Oxford University Press, New York, 2012

Modern Epidemiology, 4th Edition. Lash TL, VanderWeele TJ, Haneuse S, **Rothman KJ**, Wolters-Kluwers, Philadelphia, PA, 2021

Book Chapters

"Alcohol," **Rothman KJ**, in *Persons at High Risk of Cancer: An Approach to Cancer Etiology and Control*, Joseph Fraumeni, Jr. (ed.), Academic Press, New York, 1975.

"Five-year Follow-up of Infant Cardiacs: Intelligence Quotient," Fyler DC, Silbert AR and **Rothman KJ**, in *The Child with Congenital Heart Disease After Surgery*, Kidd BSL and Rowe RD (eds.), Futura, Mt. Kisco, NY, 1976.

"Causes and Risks," **Rothman KJ**, in *Pulmonary Disease: Defense Mechanisms and Populations at Risk*, Clark MA (ed.), Tobacco and Health Research Institute, Lexington, KY, 1977.

"The Determinants of Five Year Survival of Infants with Critical Congenital Heart Disease," Fyler DC, **Rothman KJ**, Buckley LP, *et al*., in *Pediatric Cardiovascular Disease*, Engle MA (ed.), FA Davis Co., Philadelphia, PA, 1980.

"Diseases of the Mouth," **Rothman KJ**, in *Preventive and Community Medicine*, Clark DW and MacMahon B (eds.), 2nd edition, Little, Brown and Co., Boston, MA, 1981.

"Causation and Causal Inference," in *Cancer Epidemiology and Prevention*, Schottenfeld D and Fraumeni JF, Jr. (eds.), WB Saunders Co., Philadelphia, PA, 1982.

"Significance of Studies of Low-Dose Radiation Fallout in the Western United States," **KJ Rothman**, in *Radiation Carcinogenesis: Epidemiology and Biological Significance*, Boice JD Jr., and Fraumeni JF Jr. (eds.), Raven Press, New York, NY 1984.

"Interpretation of Epidemiologic Studies on Smokeless Tobacco and Cancer," **KJ Rothman**, in *Health Implications of Smokeless Tobacco*, NIH Consensus Development Conference, 1986.

"Epidemiology of Laryngeal Cancer," Cann CI, **Rothman KJ**, Fried MP, in *The Larynx*, Fried MP (ed.), Little, Brown and Co., Boston, MA, 1988.

Foreword to *Pharmacoepidemiology. An Introduction*, **Rothman KJ;** Hartzema AG, Porta MS and Tilson HH (eds.), Harvey Whitney Books, Cincinnati, 1988.

"Malattie della bocca," **Rothman KJ**, in *Medicina Preventiva e di Comunità*, Clark DW and MacMahon B, Liviana Università Press, 1994.

"Epidemiology of Laryngeal Cancer," Cann CI, **Rothman KJ**, Fried MP, Chap 37 in *The Larynx, a Multidisciplinary Approach* (Second Edition), Fried MP (ed.), Mosby, St. Louis, 1995.

"Causation and Causal Inference," **Rothman KJ** and Poole C, in *Cancer Epidemiology and Prevention*, 2nd edition, Schottenfeld D and Fraumeni JF, Jr. (eds.), Oxford University Press, New York, 1996.

"Causation and Causal Inference," **Rothman KJ** and Greenland S, in *The Oxford Textbook of Public Health, 3rd Edition,* Detels R, Holland WW, McEwen J, and Omenn GS, eds., Oxford University Press, Oxford, 1997

"Hill's Criteria for Causality," **Rothman KJ**, Greenland S, in *The Encyclopedia of Biostatistics*, 3:1920-1924, Armitage P and Colton T, eds., John Wiley & Sons, Chichester, UK, 1998

"Validity and Generalizability in Epidemiologic Studies," **Rothman KJ**, Greenland S, in *The Encyclopedia of Biostatistics*, 6:4700-4706, Armitage P and Colton T, eds., John Wiley & Sons, Chichester, UK, 1998

"State of the Science in RF Epidemiology," **Rothman KJ**, in *Wireless Phones and Health. Scientific Progress.* Carlo GL, ed, Kluwer Academic Publishers, Boston, 1998.

"Hyperhomocysteinemia, Diabetes, and Cardiovascular Disease," Hoogeveen EK and **Rothman KJ**, in *Primary and Secondary Preventive Nutrition*, Bendich A and Deckelbaum RJ, eds., Humana Press, Totowa NJ, 2001

"A First Course in Epidemiologic Principles and Methods," **Rothman KJ**, in *Teaching Epidemiology. A Guide for Teachers in Epidemiology, Public Health and Clinical Medicine.* Second Edition. Olsen J, Saracci R, Trichopoulos D, eds., Oxford University Press, Oxford, UK, 2001

"When is it Appropriate to Use a Placebo Arm in a Trial?", **Rothman KJ** and Michels KB, in *The Science of the Placebo: Toward an Interdisciplinary Research Agenda*, Guess HA, Kleinman A, Kusek JW and Engel LW, eds., BMJ Books, London, 2002

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"Epidemiologic Study Designs", **Rothman KJ**, Greenland S, and Lash TL, in Handbook of Epidemiology and Medical Statistics, Rao CR, Miller JP, and Rao DC, eds., Elsevier, New York, 2008.

"Case-control Studies", **Rothman KJ**, Greenland S, and Lash TL, in Encyclopedia of Quantitative Risk Analysis and Assessment, Everitt B and Melnick E, eds., Wiley, New York, 2008.

"Planning a Registry", Gross T, Kremer JM, McDonough CG, Haas J, **Rothman KJ**, Chapter 2 in Registries for Evaluating Patient Outcomes: A User's Guide, 2nd Edition. Agency for Healthcare Research and Quality, USDHHS, AHRQ Publication No. 10-EHC049, 2010.

"Modern Epidemiology and Global Health in the era of Information System and mHealth", Fox MP and **Rothman KJ**, Chapter 4 in Global Health Informatics, MIT Press, 2017

Journal Publications

Rothman KJ, Keller AZ: The effect of joint exposure to alcohol and tobacco on risk of cancer of the mouth and pharynx. J Chron Dis 1972; 25:711-716.

Rothman KJ, Glass RL, Espinal F, Velez H: Caries-free teeth in the absence of fluoride ion. J Pub Health Dent 1972; 32:225-228.

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Jick H, Watkins RN, Hunter JR, Dinan BJ, Madsen S, **Rothman KJ**, Walker AM: Replacement estrogens and endometrial cancer. N Engl J Med 1979; 300:218-222.

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EXHIBIT C

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